IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Bradford C. Webb
Serial No	:	08/870,199
Filed	:	June 5, 1997
Examiner	:	Zohreh A Fay
Group Art Unit	:	1618
Confirmation No	:	6700
Title	:	SYNTHETIC VISCOELASTIC MATERIAL FOR OPHTHALMIC APPLICATIONS

APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is submitted in response to the Final Office Action dated April 19, 2007, for which the three-month date for response was July 19, 2007. A Response to the Final Office Action was timely filed on August 24, 2007, with a request and fee for a two-month extension of time. An Advisory Action was mailed on September 28, 2007. A Notice of Appeal was timely filed electronically on October 15, 2007. The due date for this Appeal Brief is December 15, 2007.

I. REAL PARTY IN INTEREST

The real party in interest in this case is Nestlé S.A, with a principal place of business in Switzerland.

II. RELATED APPEALS AND INTERFERENCES

Appellant knows of no related appeals or interferences.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 56 claims pending in the application, which are identified as claims 1-56.

B. Current Status of Claims

Claims 1-56 have been rejected.

C. Claims Appealed

The appealed claims are claims 1-56.

IV. STATUS OF AMENDMENTS

On August 24, 2007, Appellant filed a Response after the final Office Action. In the Response, Appellant amended the reissue application claims to provide corrected status identifiers and claim format relative to the original claims of the issued patent. The Examiner responded to the Response in an Advisory Action mailed September 28, 2007. In the Advisory Action, the Examiner indicated that Appellant's proposed amendments to the claims would be entered and considered.

Accordingly, the claims attached hereto in the Claims Appendix (Section VIII) reflect all amendments to the claims made to date by Appellant in this matter. There are no outstanding amendments to the claims.

V. SUMMARY OF CLAIMED SUBJECT MATTER

All citations below refer to U.S. Patent No. 5,422,376.

According to claim 1, an improved composition for physiological applications, said composition containing hydroxypropylmethylcellulose in a physiological salt solution, the improvement comprising a hydroxypropylmethylcellose solution free of harmful particulate matter and gels greater than 0.5 μm in diameter (p. 5, col. 6, lns. 3-12) said viscoelastic solution having a zero shear viscosity in excess of 15,000 cps, an average molecular weight in excess of 250,000 Daltons and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human body (p. 5, col. 5, lns. 20-38).

According to claim 13, a process for preparing a viscoelastic solution of hydroxypropylmethylcellulose in a physiological salt solution, the composition having a zero shear viscosity in excess of 15,000 cps (p. 5, col. 5, lns. 20-38) and being free of harmful

particulate material and gels greater than 0.5 μm in diameter (p. 5, col. 6, lns. 3-12) and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human eye, the process comprising the steps of:

a) dispersing the hydroxypropylmethylcellulose in the salt solution to form a suspension, (p. 6, col. 7, lns. 1-52)
b) heating the suspension of step (a) to about 95°C., allowing any undissolved material to settle and discarding the supernatant liquid above the undissolved material, (p. 6, col. 7, lns. 1-52)
c) resuspending the undissolved material to form a second suspension of hydroxypropylmethylcellulose and heating the second suspension to form a thick gel, (p. 6, col. 7, lns. 1-52)
d) filtering the gel through a series of filters to form a clean solution, (p. 5, col. 6, lns. 1-12; p. 6, col. 7, lns. 1-52)
e) autoclaving the clean solution, (p. 6, col. 7, lns. 1-52)
f) cooling the autoclaved clean solution and filtering the cooled solution, (p. 6, col. 7, lns. 1-52) and
g) degassing the filtered cooled solution. (p. 6, col. 7, lns. 1-52)

According to claim 25, a viscoelastic composition for injection into a human eye, the viscoelastic composition comprising hydroxypropylmethylcellulose in a physiological salt solution,

the hydroxypropylmethylcellulose having an average molecular weight greater than about 375,000 but less than about 420,000 and being present in a concentration from about 2.0% to about 2.5% (p. 5, col. 5, lns. 21-55),

the composition having a viscosity from about 25,000 centipoise to about 40,000 centipoise being free of harmful particulate matter and gels greater than 0.5 μm in diameter and being pyrogen free and nontoxic (p. 5, col. 5, lns. 20-38; p. 5, col. 6, lns. 3-12).

According to claim 27, a process of preparing a sterile solution of hydroxypropylmethylcellulose in an aqueous solution, the sterile solution having a zero shear viscosity in excess of 15,000 cps and being non-toxic, non-pyrogenic, and substantially free

of particulate matter and gels greater than 0.5 μm in diameter (p. 5, col. 6, lns. 3-12) and harmful to the human eye, the process comprising the steps of:

a) dispersing hydropropylmethylcellulose in a first part of the aqueous solution to form a suspension; (p. 6, col. 7, lns. 1-52)
b) allowing the suspension to settle to yield a supernatant and a sediment; comprising high molecular weight hydroxypropylmethylcellulose; (p. 6, col. 7, lns. 1-52)
c) discarding the supernatant, and leaving the sediment; (p. 6, col. 7, lns. 1-52)
d) resuspending the sediment in a second part of the aqueous solution to form a gel; (p. 6, col. 7, lns. 1-52)
e) filtering the gel through a plurality of successively finer filters to remove harmful particulate and gelatinous matter to form a clean solution; (p. 6, col. 7, lns. 1-52) and
f) sterilizing the clean solution. (p. 6, col. 7, lns. 1-52)

According to claim 31, an improved composition for physiological applications, said composition containing hydroxypropylmethylcellulose in a physiological salt solution, the improvement comprising a hydroxypropylmethylcellulose solution free of particulate matter and gels greater than 0.5 μm in diameter (p. 5, col. 6, lns. 3-12) , said viscoelastic solution having a zero shear viscosity in excess of 15,000 cps, an average molecular weight in excess of 250,000 Daltons and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human body (p. 5, col. 5, lns. 20-38).

According to claim 43, a process for preparing a viscoelastic solution of hydroxypropylmethylcellulose in a physiological salt solution, the composition being free of particulate material and gels greater than 0.5 μm in diameter (p. 5, col. 6, lns. 3-12) and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human eye, the process comprising the steps of:

a) dispersing the hydroxypropylmethylcellulose in the salt solution to form a suspension, (p. 6, col. 7, lns. 1-52)
b) heating the suspension of step (a) to about 95° C, allowing any undissolved material to settle and discarding the supernatant liquid above the undissolved material, (p. 6, col. 7, lns. 1-52)
c) resuspending the undissolved material to form a second suspension of hydroxypropylmethylcellulose and heating the second suspension to form a thick gel, (p. 6, col. 7, lns. 1-52)
d) filtering the gel through a series of filters, the series including a final filter having 0.5μm openings to form a clean solution, (p. 6, col. 7, lns. 1-52)
e) autoclaving the clean solution, (p. 6, col. 7, lns. 1-52)
f) cooling the autoclaved clean solution and filtering the cooled solution, (p. 6, col. 7, lns. 1-52) and
g) degassing the filtered cooled solution. (p. 6, col. 7, lns. 1-52)

According to claim 55, a viscoelastic composition for injection into a human eye, the viscoelastic composition comprising hydroxypropylmethylcellulose in a physiological salt solution,

the hydroxypropylmethylcellulose having an average molecular weight greater than about 375,000 but less than about 420,000 and being present in a concentration from about 2.0% to about 2.5%, (p. 5, col. 5, lns. 21-55)

the composition having a viscosity from about 25,000 centipoise to about 40,000 centipoise, being free of particulate matter and gels greater than 0.5 μm in diameter and being pyrogen free and nontoxic. (p. 5, col. 5, lns. 20-38; p. 5, col. 6, lns. 3-12)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claim 13 was improperly broadened by amendment under 35 U.S.C. § 251.
B. Whether claims 13-23 and 27-30 are unsupported by the specification under 35 U.S.C. § 112, first paragraph.
C. Whether claims 1-56 were properly rejected as being based on a defective reissue declaration.

VII. ARGUMENT

A. Claim 13 was not improperly broadened by amendment under 35 U.S.C. § 251.

Claim 13 has been rejected under 35 U.S.C. § 251 as being improperly broadened in a reissue application filed outside the two year statutory period. The focus of the Examiner's rejection appears to be Appellant's removal of the limitation "the series including a final filter having a 0.5 μm opening" from reissue claim 13.

The above-recited limitation was first removed from reissue claim 13 by amendment in the original reissue application filed on June 5, 1997. 35 U.S.C. § 251 provides that "no reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent." The original patent (U.S. Patent No. 5,422,376) was granted June 6, 1995. The reissue application was applied for on June 5, 1997. Thus, 35 U.S.C. § 251 does not operate to prevent broadening amendments.

The Examiner has asserted that the limitation at issue "was relied upon for the allowance of the parent application, and thus cannot be removed". As stated above, Appellant believes the Examiner is rejecting claim 13 based on the recapture rule. The recapture rule precludes an applicant from securing, through a broadening reissue, subject matter that was surrendered during the prosecution of the parent application. *See Hester Industries Inc. v. Stein Inc.,* 46 USPQ2d 1641, 1648 (Fed. Cir. 1998) citing *In re Clement*, 45 USPQ2d 1161, 1164 (Fed. Cir. 1997). Classically, the recapture rule comes into play when claims that have been cancelled or amended during prosecution in order to overcome prior art are reasserted in a reissue application. In those instances, if it is determined that the claims were cancelled or amended to secure allowance of narrower claims (and the original claims were not reasserted in a continuation application), then such cancellation/amendment constitutes evidence that the subject matter of the cancelled claim has been surrendered. Under those circumstances, it would be impermissible to allow an applicant to attempt to reclaim or recapture the surrendered subject matter through a reissue application. The foregoing classical fact pattern is not present in this case, as claim 13 was allowed without argument or amendment during prosecution. Appellant acknowledges the finding in *Hester* that under certain circumstances, argument alone can be sufficient to constitute such a surrender. Those circumstances, however, are not present in this case.

In *Hester*, the reissue applicant attempted to delete from the reissue claims two limitations, both of which had been argued in the parent case prosecution as being critical to distinguish the invention over the prior art. Under those circumstances, the court found that the applicant's "repeated arguments" in the parent case prosecution constituted "an admission...that these limitations were necessary to overcome the prior art." Id. at 1649. Thus, the court found that the deleted limitations were the "primary bases indicated for patentability." Id. Moreover, the court in *Hester* did not find any offsetting narrowing of the reissue claims that might afford an exception to the recapture rule.

The facts and holding of *Hester* are inapposite to the present case. In the final Office Action of April 19, 2007, the Examiner states that the deleted limitation of claim 13 "was relied upon for the allowance of the parent application, and thus cannot be removed". There is, however, no indication in the prosecution record of the '376 patent of such reliance by the Examiner.

In the classical case involving claim amendments during prosecution, it is established that "the recapture rule does not apply in the absence of evidence that the amendment was an admission that the scope of the claim was not patentable." *See Hester*, 46 USPQ2d at 1648, citing *Clements*, 45 USPQ2d at 1164. Conversely, in the more difficult case, where recapture is being argued based strictly on argument made during prosecution, the rule cannot apply in the absence of evidence that a particular claim limitation was essential to distinguish over the prior art. In this case, the Examiner would need to present evidence that without the 0.5μm limitation the Appellant would have considered the invention to be unpatentable. This is simply not the case. To the contrary, the key characteristics of the hydroxypropylmethylcellulose solutions of the present invention relate to viscosity and molecular weight. Admittedly, filtration of the inventive solutions through a 0.5μm filter will yield a preferred embodiment. Nothing in the record, however, states that such a filtration step by itself is critical. Nor is there any suggestion that the high viscosity, high molecular weight hydroxypropylmethylcellulose solutions of the present invention would not be patentable without that limitation. Clearly the limitation at issue has not been considered essential for patentability.

Assuming solely for the sake of argument that the broadening aspect of the present reissued claims would otherwise be violative of the recapture rule, the corresponding narrowing aspect of the present claims is sufficient to avoid application of the rule.

Specifically, the 0.5μm limitation has not simply been removed. It has been replaced with another limitation that ensures utility of the claimed invention and provides the applicant the "scope of protection to which he is rightfully entitled." *See Hester*, 46 USPQ2d at 1650. The Appellant notes that further limitations have been included to impose the viscosity limitations in claims 13 and 27. Once again, these offsetting narrowing limitations provide justification for an exception to the recapture rule in accordance with the principle articulated in *Ball Corp. v. United States*, 221 USPQ 289 (Fed. Cir. 1984). In summary, Appellant respectfully submits that application of the recapture rule based strictly upon argument made during prosecution in the parent prosecution should only be made in instances where the subject matter has been unmistakably surrendered and where that subject matter is undeniably critical to the patentability of the claims issued in the parent application. The present facts simply do not warrant application of the recapture rule.

Appellant also respectfully submits that the Examiner's argument, if centered on the recapture doctrine, also fails to adhere to guidance provided by MPEP § 1412.02. Appellant respectfully asserts that the Reissue Recapture chart in MPEP § 1412.02 and attached hereto in the Evidence Appendix, provides appropriate guidance when determining whether a impermissible recapture has occurred. Appellant has marked the decision boxes applicable here with circled numbers one through five. Taken in isolation, the removal of the limitation "the series including a final filter having a 0.5 μm opening" from original claim 13 broadens the scope of reissue claim 13. Accordingly, the answer to the decision box marked "1" is "yes". As discussed above, the reissue application was filed within two years of the patent grant. Accordingly, the answer to the decision box marked "2" is "yes". Amendments were made to the claims in the original application; thus, the answer to the decision box marked "3" is "yes". No claims were canceled in the original application to define over the art, so the answer to the decision box marked "4" is "no". The limitation at issue was not added by amendment to narrow the claims during prosecution resulting in the issued patent, nor was the limitation at issue ever used to argue in the original application. In fact, the subject matter of reissue claim 13 was never argued or amended, as the Examiner indicated that claims 12-23 were allowable in the first Office Action mailed July 13, 1994 in the parent case (a copy of which is included in the Evidence Appendix hereto). Nor was the objected-to limitation of reissue claim 13 ever used generally in the parent case to define the invention over the prior art. In Appellant's responses, the invention was generally distinguished over the prior art on the basis of the particulate matter present in the compositions of the present invention, not the filters used to produce such a solution. Accordingly, the answer to the

decision box marked "5" is "no". Thus, on the basis of this analysis, the MPEP § 1412.02 Reissue Recapture chart states that "there is no recapture". Accordingly, the removal of the limitation at issue was proper under 35 U.S.C. § 251 based on the MPEP § 1412.02 Reissue Recapture chart.

For the above reasons, Appellant believes that claim 13 was properly amended in the reissue application, and that Appellant's amendment to claim 13 does not violate 35 U.S.C. § 251.

B. Claims 13-23 and 27-30 are fully supported by the specification under 35 U.S.C. § 112, first paragraph

Claims 13-23 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Claim 13 comprises the phrase "filtering the gel through a series of filters". Claims 14-23 depend directly or indirectly from claim 13, and thus also comprise this phrase. Col. 6, lines 3-12 specifically discusses filter series that may be used with embodiments of the present invention and also specifically discusses a filter series that was found to be suitable. If the Examiner's rejection was based upon an assertion that the specification does not include the exact words of the claim, Appellant respectfully asserts that "the test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language." *See In re Kaslow,* 707 F.2d 1366, 1375 (Fed. Cir. 1983).

Claims 27-30 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Claim 27 comprises the phrase "harmful to the human eye" as part of the larger phrase "substantially free of particulate matter and gels greater than 0.5 μm in diameter and harmful to the human eye." Claims 28-30 depend directly or indirectly from claim 27, and thus also comprise this phrase. Col. 4, lines 12-20 specifically describes harmful particulate matter. Generally, the specification describes harmful particulate matter and gels from col. 1, line 9-col. 4, lines 19. Again, as *Kaslow* states, the subject matter of the claim need not be described literally.

C. Claims 1-56 are fully supported by the Reissue Declarations already of record.

Claims 1-56 are rejected as being based on a defective reissue declaration. The Examiner states that the original declaration does not indicate certain limitations that were added to the claims.

A Supplemental Declaration under 37 C.F.R. § 1.175(b) and dated April 4, 2004 ("Supplemental Declaration") was filed in this case with the May 6, 2004 Response. A copy of the Supplemental Declaration is attached in the Evidence Appendix.

The Supplemental Declaration comprises Exhibit B which is a listing of claims that corresponds to the listing of claims above. The undersigned has compared the listing of claims above with the claims listed in Exhibit B of the Supplemental Declaration and found them to be substantially identical with the exception of status identifiers and bracketing/underlining. Appellant affirms in the Supplemental Declaration that he has reviewed and understands the scope of the Exhibit B claims. Paragraph 6 of the Supplemental Declaration also references the amendments discussed above, including by reference the amendments in Exhibit B. Paragraph 6 is substantially of the form required by 37 C.F.R. § 1.175(b) and MPEP 1414.01.

In the responses filed by Appellant subsequent to the filing of the Supplemental Declaration, no further amendments have been made to the claims other than a wholesale deletion of claims 57 and 58. Claims 57 and 58 were not present in the issued patent and their deletion does not result in a correction to an error in the issued patent that is required to be addressed by a § 1.175(b) declaration.

In view of the above, Appellant respectfully asserts that the Supplemental Declaration is in compliance with the requirements of 37 C.F.R. § 1.175(b) and guidelines of M.P.E.P. § 1414.01 relative to the listing of claims above. Accordingly, claims 1-56 are fully supported by the Reissue Declarations already of record.

VIII. CLAIMS APPENDIX

The claims on appeal are as follows:

1. (Twice Amended) An improved composition for physiological applications, said composition containing hydroxypropylmethylcellulose in a physiological salt solution, the improvement comprising a hydroxypropylmethylcellose solution free of harmful particulate matter and gels greater than 0.5 μm in diameter, said viscoelastic solution having a zero shear viscosity in excess of 15,000 cps, an average molecular weight in excess of 250,000 Daltons and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human body.

2. (Original) The improved composition of claim 1 wherein said composition being pyrogen free and non-toxic when a therapeutically effective amount of the solution is injected into a human eye.

3. (Original) The viscoelastic solution of claim 2 wherein the hydroxypropylmethylcellulose is present in a concentration from about 2.0% to about 2.5%.

4. (Original) The viscoelastic solution of claim 2 wherein the viscosity of the solution is from about 25,000 centipoise to about 40,000 centipoise.

5. (Original) The viscoelastic solution of claim 2 wherein the average molecular weight of the hydroxypropylmethylcellulose is greater than about 375,000 but less than 420,000.

6. (Original) The viscoelastic solution of claim 2 prepared from a blend of a first hydroxypropylmethylcellulose having a first molecular weight and a second hydroxypropylmethylcellulose having a greater molecular weight, the blend being processed to produce the particulate free, pyrogen free, and non-toxic solution.

7. (Original) The viscoelastic solution of claim 6 wherein the blend is processed by filtration, redissolving and removal of low molecular weight material, mid-process autoclaving and removal of dissolved gases.

8. (Original) The viscoelastic solution of claim 7 wherein the hydroxypropylmethylcellulose in the viscoelastic solution after processing has an average molecular weight greater than the average molecular weight of the first hydroxypropylmethylcellulose or the second hydroxypropylmethylcellulose.

9. (Original) The viscoelastic solution of claim 6 wherein the first hydroxypropylmethylcellulose has an average molecular weight of about 85,000 and the second hydroxypropylmethylcellulose has an average molecular weight of about 220,000.

10. (Original) The viscoelastic solution of claim 8 wherein the average molecular weight of the hydroxypropylmethylcellulose after processing is greater than 375,000 but less than 420,000.

11. (Original) The viscoelastic solution of claim 6 having a hydroxypropylmethylcellulose concentration of about 2.3%.

12. (Original) The viscoelastic solution of claim 5 wherein the hydroxypropylmethylcellulose has an average molecular weight of about 410,000.

13. (Thrice Amended) A process for preparing a viscoelastic solution of hydroxypropylmethylcellulose in a physiological salt solution, the composition having a zero shear viscosity in excess of 15,000 cps and being free of harmful particulate material and gels greater than 0.5 μm in diameter and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human eye, the process comprising the steps of:

a) dispersing the hydroxypropylmethylcellulose in the salt solution to form a suspension,
b) heating the suspension of step (a) to about 95°C., allowing any undissolved material to settle and discarding the supernatant liquid above the undissolved material,
c) resuspending the undissolved material to form a second suspension of hydroxypropylmethylcellulose and heating the second suspension to form a thick gel,

d) filtering the gel through a series of filters [, the series including a final filter having 0.5 μm openings] to form a clean solution,
e) autoclaving the clean solution,
f) cooling the autoclaved clean solution and filtering the cooled solution, and
g) degassing the filtered cooled solution.

14. (Original) The process of claim 13 wherein the physiological salt solution has a pH of about 8.7 and contains NaCl, KCl, $CaCl_2.2H_2O$, $MgCl.6H_2O$, $NaC_2H_3O_2.3H_2,O$, $Na_3C_6HO_7.2H_2O$.

15. (Original) The process of claim 13 wherein the hydroxypropylmethylcellulose dispersed in the aqueous salt solution is a blend of a first hydroxypropylmethylcellulose having a first molecular weight and a second hydroxypropylmethylcellulose having a higher molecular weight.

16. (Original) The process of claim 15 wherein the first hydroxypropylmethylcellulose has a molecular weight of about 85,000 Daltons and the second hydroxypropylmethylcellulose has a molecular weight of about 220,000 Daltons.

17. (Original) The process of claim 15 wherein the weight of the first hydroxypropylmethylcellulose in the suspension is about the weight of the second hydroxypropylmethylcellulose.

18. (Original) The process of claim 15 wherein the hydroxypropylmethylcellulose in the suspension is about 3% by weight.

19. (Original) The process of claim 13 wherein the concentration of the hydroxypropylmethylcellulose in the degassed solution is from about 2.0% to about 2.5%.

20. (Original) The process of claim 13 wherein the concentration of the hydroxypropylmethylcellulose in the degassed solution is about 2.3%.

21. (Original) The process of claim 13 wherein the viscosity of the degassed solution is from about 25,000 centipoise to about 40,000 centipoise.

22. (Original) The process of claim 13 wherein the viscosity of the degassed solution is about 40,000 centipoise.

23. (Original) The process of claim 13 wherein the molecular weight of the hydroxypropylmethylcellulose in the degassed solution is greater than about 375,000 but less than about 420,000.

24. (Original) The process of claim 11 wherein the molecular weight of the hydroxypropylmethylcellulose in the degassed solution is about 410,000.

25. (Twice Amended) A viscoelastic composition for injection into a human eye, the viscoelastic composition comprising hydroxypropylmethylcellulose in a physiological salt solution,

the hydroxypropylmethylcellulose having an average molecular weight greater than about 375,000 but less than about 420,000 and being present in a concentration from about 2.0% to about 2.5%,

the composition having a viscosity from about 25,000 centipoise to about 40,000 centipoise being free of harmful particulate matter and gels greater than 0.5 μm in diameter and being pyrogen free and nontoxic.

26. (Original) The viscoelastic composition of claim 25 wherein the concentration of the hydroxypropylmethylcellulose is about 2.3%, the average molecular weight of the hydroxypropylmethylcellulose is about 409,800 and the zero shear viscosity of the composition is about 40,000 centipoise.

27. (Amended Four Times) A process of preparing a sterile solution of hydroxypropylmethylcellulose in an aqueous solution, the sterile solution having a zero shear viscosity in excess of 15,000 cps and being non-toxic, non-pyrogenic, and substantially free of particulate matter and gels greater than 0.5 μm in diameter and harmful to the human eye, the process comprising the steps of:

a) dispersing hydropropylmethylcellulose in a first part of the aqueous solution to form a suspension;

b) allowing the suspension to settle to yield a supernatant and a sediment; comprising high molecular weight hydroxypropylmethylcellulose;

c) discarding the supernatant, and leaving the sediment;
d) resuspending the sediment in a second part of the aqueous solution to form a gel;
e) filtering the gel through a plurality of successively finer filters to remove harmful particulate and gelatinous matter to form a clean solution; and
f) sterilizing the clean solution.

28. (Amended) The process of claim 27, wherein step a) is performed at a sufficiently elevated temperature to solvate low molecular weight hydroxypropylmethylcellulose, and step e) is performed at a sufficiently elevated temperature to significantly reduce the viscosity of the gel.

29. (Amended) The process of claim 28, wherein the sterilization of the clean solution is effected by autoclaving.

30. (Amended) The process of claim 29, comprising the further steps of:

a) cooling the autoclaved clean solution;
b) filtering the cooled solution; and
c) degassing the filtered, cooled solution.

31. (Amended) An improved composition for physiological applications, said composition containing hydroxypropylmethylcellulose in a physiological salt solution, the improvement comprising a hydroxypropylmethylcellulose solution free of particulate matter and gels greater than 0.5 μm in diameter, said viscoelastic solution having a zero shear viscosity in excess of 15,000 cps, an average molecular weight in excess of 250,000 Daltons and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human body.

32. (Amended) The improved composition of claim 31 wherein said composition being pyrogen free and non-toxic when a therapeutically effective amount of the solution is injected into a human eye.

33. (Amended) The viscoelastic solution of claim 32 wherein the hydroxypropylmethylcellulose is present in a concentration from about 2.0% to about 2.5%.

34. (Amended) The viscoelastic solution of claim 32 wherein the viscosity of the solution is from about 25,000 centipoise to about 40,000 centipoise.

35. (Amended) The viscoelastic solution of claim 32 wherein the average molecular weight of the hydroxypropylmethylcellulose is greater than about 375,000 but less than 420,000.

36. (Amended) The viscoelastic solution of claim 32 prepared from a blend of a first hydroxypropylmethylcellulose having a first molecular weight and a second hydroxypropylmethylcellulose having a greater molecular weight, the blend being processed to produce the particulate free, pyrogen free, and non-toxic solution.

37. (Amended) The viscoelastic solution of claim 36 wherein the blend is processed by filtration, redissolving and removal of low molecular weight material, mid-process autoclaving and removal of dissolved gases.

38. (Amended) The viscoelastic solution of claim 37 wherein the hydroxypropylmethylcellulose in the viscoelastic solution after processing has an average molecular weight greater than the average molecular weight of the first hydroxypropylmethylcellulose or the second hydroxypropylmethylcellulose.

39. (Amended) The viscoelastic solution of claim 36 wherein the first hydroxypropylmethylcellulose has an average molecular weight of about 85,000 and the second hydroxypropylmethylcellulose has an average molecular weight of about 220,000.

40. (Amended) The viscoelastic solution of claim 38 wherein the average molecular weight of the hydroxypropylmethylcellulose after processing is greater than 375,000 but less than 420,000.

41. (Amended) The viscoelastic solution of claim 36 having a hydroxypropylmethylcellulose concentration of about 2.3%.

42. (Amended) The viscoelastic solution of claim 35 wherein the hydroxypropylmethylcellulose has an average molecular weight of about 410,000.

43. (Amended) A process for preparing a viscoelastic solution of hydroxypropylmethylcellulose in a physiological salt solution, the composition being free of particulate material and gels greater than 0.5 μm in diameter and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human eye, the process comprising the steps of:

a) dispersing the hydroxypropylmethylcellulose in the salt solution to form a suspension,
b) heating the suspension of step (a) to about 95° C, allowing any undissolved material to settle and discarding the supernatant liquid above the undissolved material,
c) resuspending the undissolved material to form a second suspension of hydroxypropylmethylcellulose and heating the second suspension to form a thick gel,
d) filtering the gel through a series of filters, the series including a final filter having 0.5μm openings to form a clean solution,
e) autoclaving the clean solution,
f) cooling the autoclaved clean solution and filtering the cooled solution, and
g) degassing the filtered cooled solution.

44. (Amended) The process of claim 43 wherein the physiological salt solution has a pH of about 8.7 and contains NaCl, KCl, $CaCl_2.2H_2O$, $MgCl.6H_2O$, $NaC_2H_3O_2.3H_2,O$, $Na_3C_6HO_7.2H_2O$.

45. (Amended) The process of claim 43 wherein the hydroxypropylmethylcellulose dispersed in the aqueous salt solution is a blend of a first hydroxypropylmethylcellulose having a first molecular weight and a second hydroxypropylmethylcellulose having a higher molecular weight.

46. (Amended) The process of claim 45 wherein the first hydroxypropylmethylcellulose has a molecular weight of about 85,000 Daltons and the second hydroxypropylmethylcellulose has a molecular weight of about 220,000 Daltons.

47. (Amended) The process of claim 45 wherein the weight of the first hydroxypropylmethylcellulose in the suspension is about the weight of the second hydroxypropylmethylcellulose.

48. (Amended) The process of claim 45 wherein the hydroxypropylmethylcellulose in the suspension is about 3% by weight.

49. (Amended) The process of claim 43 wherein the concentration of the hydroxypropylmethylcellulose in the degassed solution is from about 2.0% to about 2.5%.

50. (Amended) The process of claim 43 wherein the concentration of the hydroxypropylmethylcellulose in the degassed solution is about 2.3%.

51. (Amended) The process of claim 43 wherein the viscosity of the degassed solution is from about 25,000 centipoise to about 40,000 centipoise.

52. (Amended) The process of claim 43 wherein the viscosity of the degassed solution is about 40,000 centipoise.

53. (Amended) The process of claim 43 wherein the molecular weight of the hydroxypropylmethylcellulose in the degassed solution is greater than about 375,000 but less than about 420,000.

54. (Amended) The process of claim 41 wherein the molecular weight of the hydroxypropylmethylcellulose in the degassed solution is about 410,000.

IX. EVIDENCE APPENDIX

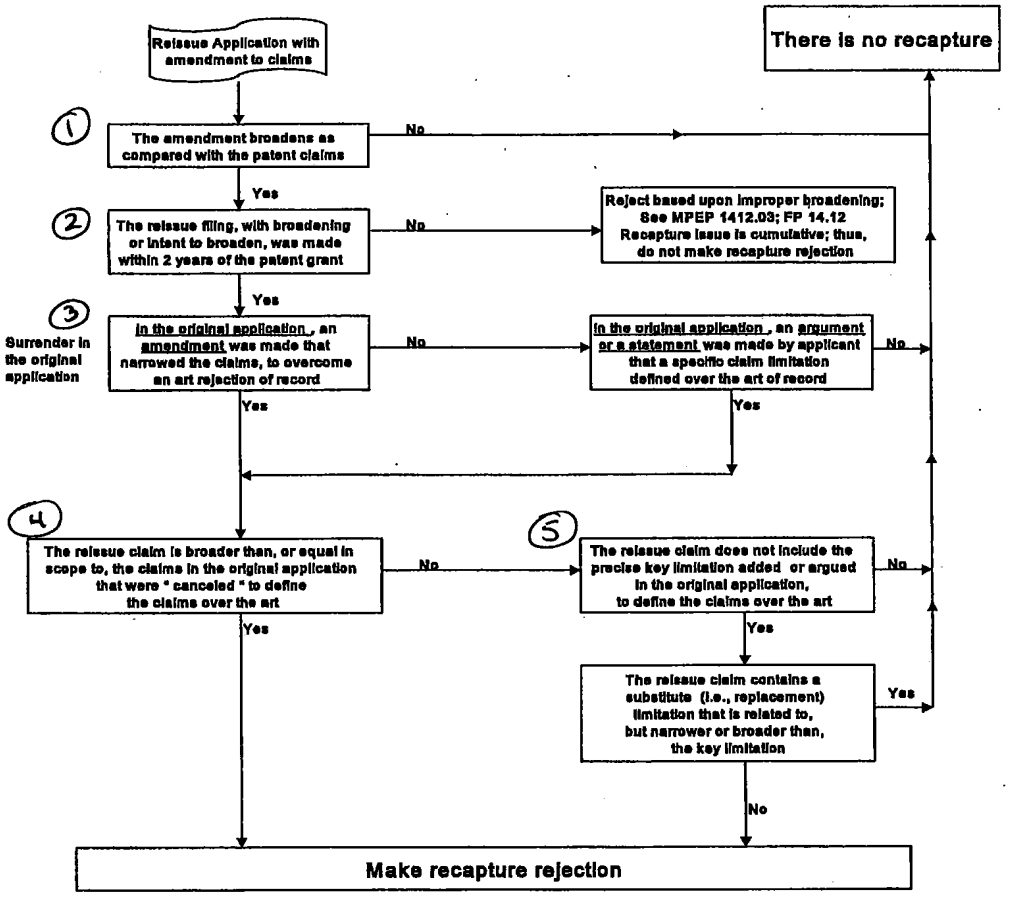
Evidence pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132 is submitted in this Appendix. The Evidence Appendix comprises:

MPEP 1412.02 Reissue Recapture Chart

Office Action mailed July 13, 1994

Supplemental Declaration of Bradford Webb executed April 4, 2004 with Exhibit B

Reissue Recapture - Determining its presence or absence



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/240,941	05/11/94	WEBB	B 4160008009

EXAMINER	
FAY, Z	
ART UNIT	**PAPER NUMBER**
1205	10

12M1/0713

ARANT, KLEINBERG, LERNER & RAM
2049 CENTURY PARK EAST, #1080
LOS ANGELES, CA 90067

DATE MAILED: 07/13/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

P-13-94
9-13-94
10-13-94

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-25 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☒ Claims 12-23 are allowable.

4. ☒ Claims 1-11, 24 and 25 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in

Claims 1-25 are presented for examination.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-11, 24 and 25 are rejected under 35 U.S.C. § 103 as being unpatentable over Fechner and Hazariwala et al.

Fechner teaches the use of hydroxypropyl methylcellulose for viscous surgery. Hazariwala et al teach the use of the mixture of hydroxypropyl methylcellulose and hyaluronic acid in implant surgery.

One skilled in the art would have been motivated to combine the teachings of the above references, since they in combination relate to the use hydroxypropyl methylcellulose individually and also in combination with other viscoelastic agents during ophthalmic surgery. The above references make clear that the claimed viscoelastic material is a well known agent being used during ophthalmic surgery. The above references also make clear that the use of the combination of different viscoelastic agents is old and well known. Applicant has presented no convincing evidence to establish the unexpected and unobvious nature of the claimed mixture and as such claims 1-25 are properly rejected under 35 USC 103.

Claims 12-23 are considered to be allowed.

Any inquiry concerning this communication should be directed to Examiner Z. Fay at telephone number (703) 308-1235.

A facsimile center has been established in Group 1200, room 3C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine is (703) 308-4556 or 305-3592.

FAY:tcj
June 30, 1994

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200

IN THE UNITED STATES PATENT OFFICE

In re:	Bradford C. Webb
Serial No.	08/870,199
Confirmation No.:	6700
Filed:	June 5, 1997
Examiner:	Z. Fay
Group Art Unit:	1614
For:	SYNTHETIC VISCOELASTIC MATERIAL FOR OPHTHALMIC APPLICATIONS

SUPPLEMENTAL DECLARATION UNDER 37 C.F.R. § 1.175(b)

Mail Stop: REISSUE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Bradford C. Webb, declare that:

1. I am a citizen of the United States of America and reside at 1187 Coast Village Road, No. 501, Santa Barbara, CA 93108. I believe that I am the original, first and sole inventor of the invention described and claimed in U.S. Letters Patent No. 5,422,376 (hereinafter called "Patent") and in the above-identified reissue application ("this application"). As such, I previously submitted, with respect to this application, my declaration dated August 15, 1997, a copy of which is attached hereto as Exhibit A (the "prior declaration"). With the exception of my current residence address stated above and an incorrect reference to claims 30-33 (the correct reference would have been to claims 27-30), I hereby reaffirm the contents of my prior declaration including the portions thereof identifying with particularity the errors which constitute the basis for this reissue application.

2. I have reviewed and understand the scope of the claims being proposed in an amendment that I understand will be submitted with this declaration, a copy of which claims is attached hereto as Exhibit B.

3. Claims 1-30 attached hereto have been amended to require that the hydroxypropylmethylcellulose solution be "free of harmful particulate matter and gels greater than 0.5μm in diameter..."

4. Claims 31-56 correspond to originally issued 26 claims of the Patent.

5. Claims 57 and 58 do not contain the 0.5μm limitation, but instead are limited to blended material corresponding to dependent claims 6 and 10 of the originally issued Patent.

6. I understand that claims 1-30 and 57-58 have been crafted to address the errors identified in my prior declaration. However, to the extent that the amendments discussed above address any errors not covered by my prior declaration, I hereby confirm that any such errors are believed to have arisen without any deceptive intent on the part of the applicant.

I, the undersigned, declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed this 4 day of April, 2004

2:05pm

Bradford C. Webb
1187 Coast Village Road, #501
Santa Barbara, CA 93108

EXHIBIT B

IN THE CLAIMS

Claim 1 (currently amended) An improved composition for physiological applications, said composition containing hydroxypropylmethylcellulose in a physiological salt solution, the improvement comprising a hydroxypropylmethylcellose solution free of harmful particulate matter and gels greater than 0.5 µm in diameter, said viscoelastic solution having a zero shear viscosity in excess of 15,000 cps, an average molecular weight in excess of 250,000 Daltons and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human body.

Claim 2 (original) The improved composition of claim 1 wherein said composition being pyrogen free and non-toxic when a therapeutically effective amount of the solution is injected into a human eye.

Claim 3 (original) The viscoelastic solution of claim 2 wherein the hydroxypropylmethylcellulose is present in a concentration from about 2.0% to about 2.5%.

Claim 4 (original) The viscoelastic solution of claim 2 wherein the viscosity of the solution is from about 25,000 centipoise to about 40,000 centipoise.

Claim 5 (original) The viscoelastic solution of claim 2 wherein the average molecular weight of the hydroxypropylmethylcellulose is greater than about 375,000 but less than 420,000.

Claim 6 (original) The viscoelastic solution of claim 2 prepared from a blend of a first hydroxypropylmethylcellulose having a first molecular weight and a second hydroxypropylmethylcellulose having a greater molecular weight, the blend being processed to produce the particulate free, pyrogen free, and non-toxic solution.

Claim 7 (original) The viscoelastic solution of claim 6 wherein the blend is processed by filtration, redissolving and removal of low molecular weight material, mid-process autoclaving and removal of dissolved gases.

Claim 8 (original) The viscoelastic solution of claim 7 wherein the hydroxypropylmethylcellulose in the viscoelastic solution after processing has an average molecular weight greater than the average molecular weight of the first hydroxypropylmethylcellulose or the second hydroxypropylmethylcellulose.

Claim 9 (original) The viscoelastic solution of claim 6 wherein the first hydroxypropylmethylcellulose has an average molecular weight of about 85,000 and the second hydroxypropylmethylcellulose has an average molecular weight of about 220,000.

Claim 10 (original) The viscoelastic solution of claim 8 wherein the average molecular weight of the hydroxypropylmethylcellulose after processing is greater than 375,000 but less than 420,000.

Claim 11 (original) The viscoelastic solution of claim 6 having a hydroxypropylmethylcellulose concentration of about 2.3%.

Claim 12 (original) The viscoelastic solution of claim 5 wherein the hydroxypropylmethylcellulose has an average molecular weight of about 410,000.

Claim 13 (currently amended) A process for preparing a viscoelastic solution of hydroxypropylmethylcellulose in a physiological salt solution, the composition having a zero shear viscosity in excess of 15,000 cps and being free of harmful particulate material and gels greater than 0.5 μm in diameter and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human eye, the process comprising the steps of:

a) dispersing the hydroxypropylmethylcellulose in the salt solution to form a suspension,

b) heating the suspension of step (a) to about 95°C., allowing any undissolved material to settle and discarding the supernatant liquid above the undissolved material,

c) resuspending the undissolved material to form a second suspension of hydroxypropylmethylcellulose and heating the second suspension to form a thick gel,

d) filtering the gel through a series of filters to form a clean solution,

e) autoclaving the clean solution,

f) cooling the autoclaved clean solution and filtering the cooled solution, and

g) degassing the filtered cooled solution.

Claim 14 (original) The process of claim 13 wherein the physiological salt solution has a pH of about 8.7 and contains NaCl, KCl, $CaCl_2.2H_2O$, $MgCl.6H_2O$, $NaC_2H_3O_2.3H_2,O$, $Na_3C_6HO_7.2H_2O$.

Claim 15 (original) The process of claim 13 wherein the hydroxypropylmethylcellulose dispersed in the aqueous salt solution is a blend of a first hydroxypropylmethylcellulose having a first molecular weight and a second hydroxypropylmethylcellulose having a higher molecular weight.

Claim 16 (original) The process of claim 15 wherein the first hydroxypropylmethylcellulose has a molecular weight of about 85,000 Daltons and the second hydroxypropylmethylcellulose has a molecular weight of about 220,000 Daltons.

Claim 17 (original) The process of claim 15 wherein the weight of the first hydroxypropylmethylcellulose in the suspension is about the weight of the second hydroxypropylmethylcellulose.

Claim 18 (original) The process of claim 15 wherein the hydroxypropylmethylcellulose in the suspension is about 3% by weight.

Claim 19 (original) The process of claim 13 wherein the concentration of the hydroxypropylmethylcellulose in the degassed solution is from about 2.0% to about 2.5%.

Claim 20 (original) The process of claim 13 wherein the concentration of the hydroxypropylmethylcellulose in the degassed solution is about 2.3%.

Claim 21 (original) The process of claim 13 wherein the viscosity of the degassed solution is from about 25,000 centipoise to about 40,000 centipoise.

Claim 22 (original) The process of claim 13 wherein the viscosity of the degassed solution is about 40,000 centipoise.

Claim 23 (original) The process of claim 13 wherein the molecular weight of the hydroxypropylmethylcellulose in the degassed solution is greater than about 375,000 but less than about 420,000.

Claim 24 (original) The process of claim 11 wherein the molecular weight of the hydroxypropylmethylcellulose in the degassed solution is about 410,000.

Claim 25 (currently amended) A viscoelastic composition for injection into a human eye, the viscoelastic composition comprising hydroxypropylmethylcellulose in a physiological salt solution,

the hydroxypropylmethylcellulose having an average molecular weight greater than about 375,000 but less than about 420,000 and being present in a concentration from about 2.0% to about 2.5%,

the composition having a viscosity from about 25,000 centipoise to about 40,000 centipoise being free of harmful particulate matter and gels greater than 0.5 μm in diameter and being pyrogen free and nontoxic.

Claim 26 (original) The viscoelastic composition of claim 25 wherein the concentration of the hydroxypropylmethylcellulose is about 2.3%, the average molecular weight of the hydroxypropylmethylcellulose is about 409,800 and the zero shear viscosity of the composition is about 40,000 centipoise.

Claim 27 (currently amended) A process of preparing a sterile solution of hydroxypropylmethylcellulose in an aqueous solution, the sterile solution having a zero shear viscosity in excess of 15,000 cps and being non-toxic, non-pyrogenic, and substantially free of particulate matter and gels greater than 0.5 μm in diameter and harmful to the human eye, the process comprising the steps of:

a) dispersing hydropropylmethylcellulose in a first part of the aqueous solution to form a suspension;

b) allowing the suspension to settle to yield a supernatant and a sediment; comprising high molecular weight hydroxypropylmethylcellulose;

c) discarding the supernatant, and leaving the sediment;

d) resuspending the sediment in a second part of the aqueous solution to form a gel;

e) filtering the gel through a plurality of successively finer filters to remove harmful particulate and gelatinous matter to form a clean solution; and

f) sterilizing the clean solution.

Claim 28 (original) The process of step 27, wherein step a) is performed at a sufficiently elevated temperature to solvate low molecular weight hydroxypropylmethylcellulose, and step e) is performed at a sufficiently elevated temperature to significantly reduce the viscosity of the gel.

Claim 29 (original) The process of claim 28, wherein the sterilization of the clean solution is effected by autoclaving.

Claim 30 (original) The process of claim 29, comprising the further steps of:

a) cooling the autoclaved clean solution;

b) filtering the cooled solution; and

c) degassing the filtered, cooled solution.

Claim 31 (previously presented) An improved composition for physiological applications, said composition containing hydroxypropylmethylcellulose in a physiological salt solution, the improvement comprising a hydroxypropylmethylcellulose solution free of particulate matter and gels greater than 0.5 μm in diameter, said viscoelastic solution having a zero shear viscosity in excess of 15,000 cps, an average molecular weight in excess of 250,000 Daltons and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human body.

Claim 32 (previously presented) The improved composition of claim 31 wherein said composition being pyrogen free and non-toxic when a therapeutically effective amount of the solution is injected into a human eye.

Claim 33 (previously presented) The viscoelastic solution of claim 32 wherein the hydroxypropylmethylcellulose is present in a concentration from about 2.0% to about 2.5%.

Claim 34 (previously presented) The viscoelastic solution of claim 32 wherein the viscosity of the solution is from about 25,000 centipoise to about 40,000 centipoise.

Claim 35 (previously presented) The viscoelastic solution of claim 32 wherein the average molecular weight of the hydroxypropylmethylcellulose is greater than about 375,000 but less than 420,000.

Claim 36 (previously presented) The viscoelastic solution of claim 32 prepared from a blend of a first hydroxypropylmethylcellulose having a first molecular weight and a second hydroxypropylmethylcellulose having a greater molecular weight, the blend being processed to produce the particulate free, pyrogen free, and non-toxic solution.

Claim 37 (previously presented) The viscoelastic solution of claim 36 wherein the blend is processed by filtration, redissolving and removal of low molecular weight material, mid-process autoclaving and removal of dissolved gases.

Claim 38 (previously presented) The viscoelastic solution of claim 37 wherein the hydroxypropylmethylcellulose in the viscoelastic solution after processing has an average molecular weight greater than the average molecular weight of the first hydroxypropylmethylcellulose or the second hydroxypropylmethylcellulose.

Claim 39 (previously presented) The viscoelastic solution of claim 36 wherein the first hydroxypropylmethylcellulose has an average molecular weight of about 85,000 and the second hydroxypropylmethylcellulose has an average molecular weight of about 220,000.

Claim 40 (previously presented) The viscoelastic solution of claim 38 wherein the average molecular weight of the hydroxypropylmethylcellulose after processing is greater than 375,000 but less than 420,000.

Claim 41 (previously presented) The viscoelastic solution of claim 36 having a hydroxypropylmethylcellulose concentration of about 2.3%.

Claim 42 (previously presented) The viscoelastic solution of claim 35 wherein the hydroxypropylmethylcellulose has an average molecular weight of about 410,000.

Claim 43 (previously presented) A process for preparing a viscoelastic solution of hydroxypropylmethylcellulose in a physiological salt solution, the composition being free of particulate material and gels greater than 0.5 μm in diameter and being pyrogen free and

non-toxic when a therapeutically effective amount of said solution is injected into a human eye, the process comprising the steps of:

a) dispersing the hydroxypropylmethylcellulose in the salt solution to form a suspension,

b) heating the suspension of step (a) to about 95° C, allowing any undissolved material to settle and discarding the supernatant liquid above the undissolved material,

c) resuspending the undissolved material to form a second suspension of hydroxypropylmethylcellulose and heating the second suspension to form a thick gel,

d) filtering the gel through a series of filters, the series including a final filter having 0.5µm openings to form a clean solution,

e) autoclaving the clean solution,

f) cooling the autoclaved clean solution and filtering the cooled solution, and

g) degassing the filtered cooled solution.

Claim 44 (previously presented) The process of claim 43 wherein the physiological salt solution has a pH of about 8.7 and contains NaCl, KCl, $CaCl_2.2H_2O$, $MgCl.6H_2O$, $NaC_2H_3O_2.3H_2,O$, $Na_3C_6HO_7.2H_2O$.

Claim 45 (previously presented) The process of claim 43 wherein the hydroxypropylmethylcellulose dispersed in the aqueous salt solution is a blend of a first hydroxypropylmethylcellulose having a first molecular weight and a second hydroxypropylmethylcellulose having a higher molecular weight.

Claim 46 (previously presented) The process of claim 45 wherein the first hydroxypropylmethylcellulose has a molecular weight of about 85,000 Daltons and the second hydroxypropylmethylcellulose has a molecular weight of about 220,000 Daltons.

Claim 47 (previously presented) The process of claim 45 wherein the weight of the first hydroxypropylmethylcellulose in the suspension is about the weight of the second hydroxypropylmethylcellulose.

Claim 48 (previously presented) The process of claim 45 wherein the hydroxypropylmethylcellulose in the suspension is about 3% by weight.

Claim 49 (previously presented) The process of claim 43 wherein the concentration of the hydroxypropylmethylcellulose in the degassed solution is from about 2.0% to about 2.5%.

Claim 50 (previously presented) The process of claim 43 wherein the concentration of the hydroxypropylmethylcellulose in the degassed solution is about 2.3%.

Claim 51 (previously presented) The process of claim 43 wherein the viscosity of the degassed solution is from about 25,000 centipoise to about 40,000 centipoise.

Claim 52 (previously presented) The process of claim 43 wherein the viscosity of the degassed solution is about 40,000 centipoise.

Claim 53 (previously presented) The process of claim 43 wherein the molecular weight of the hydroxypropylmethylcellulose in the degassed solution is greater than about 375,000 but less than about 420,000.

Claim 54 (previously presented) The process of claim 41 wherein the molecular weight of the hydroxypropylmethylcellulose in the degassed solution is about 410,000.

Claim 55 (previously presented) A viscoelastic composition for injection into a human eye, the viscoelastic composition comprising hydroxypropylmethylcellulose in a physiological salt solution,

the hydroxypropylmethylcellulose having an average molecular weight greater than about 375,000 but less than about 420,000 and being present in a concentration from about 2.0% to about 2.5%,

the composition having a viscosity from about 25,000 centipoise to about 40,000 centipoise, being free of particulate matter and gels greater than 0.5 μm in diameter and being pyrogen free and nontoxic.

Claim 56 (previously presented) The viscoelastic composition of claim 55 wherein the concentration of the hydroxypropylmethylcellulose is about 2.3%, the average molecular weight of the hydroxypropylmethylcellulose is about 409,800 and the zero shear viscosity of the composition is about 40,000 centipoise.

Claim 57 (new) An improved composition for physiological applications, said composition containing hydroxypropylmethylcellulose in a physiological salt solution, the improvement comprising a hydroxypropylmethylcellulose solution free of harmful particulate matter and gels, said viscoelastic solution having been prepared from a blend of a first hydroxypropylmethylcellulose having a first molecular weight and a second hydroxypropylmethylcellulose having a second molecular weight different from said first molecular weight, said solution being characterized by a zero shear viscosity in excess of 15,000 cps, an average molecular weight in excess of 250,000 Daltons, and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human body.

Claim 58 (new) The composition of claim 57, wherein the average molecular weight of the blended hydroxypropylmethylcellulose in the solution is greater than 375,000 Daltons, but less than 420,000 Daltons.

X. RELATED PROCEEDINGS APPENDIX

No related proceedings are referenced in Part II above; accordingly, no court or Board proceedings are appended herein.

Respectfully submitted,

December 13, 2007
Date

/Mark E. Flanigan, Reg. #51,681/
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Docket No. 1560B US